



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0367; FRL-10009-44]

1-Aminocyclopropane-1-carboxylic Acid (ACC); Temporary Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a temporary exemption from the requirement of a tolerance for residues of 1-aminocyclopropane-1-carboxylic acid (ACC) in or on apples and stone fruits when used in accordance with the terms of the Experimental Use Permit (EUP) under EPA Number 73049-EUP-12. Valent BioSciences, LLC., submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting a temporary exemption from the requirement of a tolerance for the use of ACC for a period of three years. This regulation eliminates the need to establish a maximum permissible level for residues of ACC resulting from use in accordance with the EUP No. 73049-EUP-12 under FFDCA. The temporary exemption from the requirement of a tolerance expires on July 6, 2023.

DATES: This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-

HQ-OPP-2019-0367, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

Please note that due to the public health emergency the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: BPPDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected

entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2019-0367 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the

non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2019-0367, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Background

In the *Federal Register* of August 2, 2019 (84 FR 37818) (FRL-9996-78), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 9F8760) by Valent BioSciences, LLC., 870 Technology Way, Libertyville, IL 60048. The petitioner requested that 40 CFR part 180 be amended by establishing a temporary exemption from the requirement of a tolerance for three years for residues of the plant growth regulator 1-aminocyclopropane-1-carboxylic acid (ACC), in or on apples and stone fruits. That document referenced a summary of the petition prepared by the petitioner, Valent BioSciences, LLC., which is available in the docket via <http://www.regulations.gov>. Two comments were received. One approved of the action; one opposed using pesticides on apples. Although EPA recognizes that some do not want any pesticides in or on food, section 408 of the FFDCA authorizes EPA to set tolerances or establish

exemptions for residues of pesticide chemicals when it determines that the tolerance or exemption meets the safety standard imposed by that statute. EPA has made that determination for the ACC exemption established by this final rule. The commenter provided no information supporting a conclusion that the tolerance exemption is not safe.

III. Final Rule

A. EPA's Safety Determination

Section 408(r) of the FFDCA allows EPA to establish a temporary exemption from the requirement of a tolerance for uses covered by an experimental use permit. Under Section 408(c)(2)(A)(i), EPA may establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is “safe.” Section 408(c)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C) and (D), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance or tolerance exemption, and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue” Additionally, FFDCA section 408(b)(2)(D) requires that EPA consider “available information concerning the cumulative effects of a particular pesticide’s residues and other substances that have a common mechanism of toxicity.”

EPA evaluated the available toxicity and exposure data on 1-aminocyclopropane-1-carboxylic acid (ACC) and considered its validity, completeness, and reliability, as well as the relationship of this information to human risk. EPA also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

ACC is a naturally occurring non-protein amino acid found in all plants. It acts as a plant growth regulator (PGR), pre-cursing ethylene, a plant hormone regulating a wide variety of vegetative and developmental processes. The only conversion of ACC for residues should be into ethylene, which would not be measurable as ethylene is a quickly dissipating gas. Ethylene has been reviewed by EPA and is exempt from tolerance (40 CFR 180.1016).

As a biochemical pesticide, ACC is intended for use on apples and stone fruits for fruit thinning and enhanced return bloom and is foliarly applied with an orchard air blast sprayer. ACC's mode of action is as a signaling molecule in plants to regulate fruit ripening, thinning, and enhanced return bloom. No direct application to food is expected as applications are made pre-fruiting, but it is possible that some trace amounts of the active ingredient may be taken up into the plant.

Overall, ACC is considered to be of low toxicity. Toxicological data demonstrate that ACC is of low toxicity relative to all routes of exposure. Additionally, humans have a history of safe natural exposure to ACC as it is present in all fruits and vegetables and is a regular part of the human diet. With specific regard to human oral toxicity, the Agency notes that the human digestive system has evolved to accommodate ACC in its digestive processes. Moreover, it is noted that dietary exposures to the residues of ACC are not anticipated to exceed the naturally occurring background levels as exogenously applied ACC is highly biodegradable. It has a half-

life of less than 8.5 days on the plant and is even more biodegradable in aqueous soil conditions.

With regard to the acute toxicological profile of the active ingredient ACC, the active ingredient is of low acute oral, dermal and inhalation toxicity; it is only mildly irritating to the eye and the skin; and it is not a dermal sensitizer.

With regard to the subchronic toxicity, developmental toxicity, reproductive toxicity and mutagenicity data requirements for the active ingredient ACC, all data requirements were satisfied by guideline studies. There were no adverse subchronic effects for any route of exposure. The active ingredient was determined to be non-mutagenic. Finally, no adverse effects were identified relative to either developmental toxicity or reproductive toxicity. Based on this toxicological profile, EPA did not identify any toxicological endpoints of concern for assessing risk.

As part of its qualitative risk assessment for ACC, the Agency also considered the potential for exposure to residues of ACC, including dietary and non-occupational exposures. EPA concludes that dietary exposures are likely to be negligible, due to the short half-life and biodegradable nature of the pesticide. Residential exposures are not expected under the conditions of the association EUP.

Based on ACC's low toxicity, anticipated minimal dietary exposure, and history of safe consumption in foods, no risks of concern have been identified from aggregate exposure to ACC. Similarly, no risks of concern were identified for cumulative exposures to ACC since no common mechanism of toxicity was identified for either ACC or its metabolites. Therefore, based on the lack of toxicity and expected negligible exposures, EPA has determined that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to ACC.

A full explanation of the data upon which EPA relied and its risk assessment based on those data can be found within the April 16, 2020, document entitled, “Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for 1-aminocyclopropane-1-carboxylic acid (ACC).” This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

Based on its safety determination, EPA is establishing a temporary exemption from the requirement of a tolerance for residues of the plant growth regulator 1-aminocyclopropane-1-carboxylic acid (ACC) in or on apples and stone fruits when used in accordance with the terms of the Experimental Use Permit (EUP) under EPA Number 73049-EUP-12. This temporary exemption from the requirement of a tolerance will expire on [INSERT DATE 3 YEARS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

B. Analytical Enforcement Methodology

The analytical method for the residues of ACC can be evaluated by Ultra High-Performance Liquid Chromatography-Tandem Mass Spectrometry and is available to EPA for the detection and measurement of these pesticide residues.

IV. Statutory and Executive Order Reviews

This action establishes a temporary exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to EPA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001), or Executive Order

13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997) nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the temporary tolerance exemption in this action, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, EPA has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, EPA has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described

under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 et seq.).

This action does not involve any technical standards that would require EPA's consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

V. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 28, 2020.

Robert McNally,

Director,

Biopesticides and Pollution Prevention Division,

Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA amends 40 CFR chapter I as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Add § 180.711 to subpart C to read as follows:

§ 180.711 1-Aminocyclopropane-1-carboxylic acid (ACC); temporary exemption from the requirement of a tolerance for residues.

A temporary exemption from the requirement of a tolerance is established for residues of the plant growth regulator, 1-Aminocyclopropane-1-carboxylic acid (ACC) in or on apples and stone fruits when used in accordance with the terms of the Experimental Use Permit (EUP) under EPA Number 73049-EUP-12. This temporary exemption expires on July 6, 2023.

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